EXHIBIT G

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO ALL WAVE 6 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS:	MDL 2327 JOSEPH R. GOODWIN US DISTRICT JUDGE
Sylvia Davis Case No. 2:13-cv-00574	
Laurine Goulette Case No. 2:13-cv-01776	
Theresa Wilson Case No. 2:13-cv-00823	

September 25, 2017

Deposition of JOHN R. WAGNER, M.D., held at Marriott Melville, 1350 Old Walt Whitman Road, Melville, New York, commencing at 8:30 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

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8:32 a.m.
Melville, New York
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JOHN R. WAGNER, M.D., the Witness herein, having been first duly sworn by a Notary Public in and of the State of New York, was examined and testified as follows:

EXAMINATION BY
MR. FAES:

Q. Good morning, Dr. Wagner.
A. Good morning.
Q. My name is Andy Faes, and I'm here to take your deposition now regarding the Prolift product and your opinions regarding that product.
Do you understand that?
A. Yes.
Q. And you understand that you're under oath and sworn to tell the truth, right?
A. Yes.
Q. And you've been through this

process before, so if I ask you a question that you don't understand, please let me know, okay?
A. I will.
Q. And if for some reason I --
MR. FAES: Strike that.
Q. If I ask you a question and you answer it, I'll assume you understood the question as asked.
Fair enough?
A. Yes.
Q. Doctor, I'm going to hand you what's been marked as Exhibit Number 1 to your deposition, and this is the notice of your deposition.
(Wagner Exhibit 1, Notice to Take Deposition of John Wagner, M.D., dated September 18, 2017, was marked for identification, as of this date.)
BY MR. FAES:
Q. Do you see that?
A. Yes.
Q. This has various document requests that asks you to bring various

things to your deposition.
Have you seen that before?
A. I have seen this request before, yes, this notice before.
Q. Prior to the start of your deposition, counsel produced a flash drive, which I'm going to mark as Exhibit Number 5, just because if I mark it anything earlier it's going to mess up my whole numbering system.
(Wagner Exhibit 5, flash drive, was marked for identification, as of this date.)
BY MR. FAES:
Q. What's on this flash drive, do you know?
MS. KABBASH: I can make a representation to you, Andy, that that flash drive contains everything that's on Dr. Wagner's general reliance list.
MR. FAES: Okay.
BY MR. FAES:
Q. Also counsel produced what I'll mark as Exhibit Number 6 to your

deposition.
(Wagner Exhibit 6, Invoice of John Wagner, M.D., dated July - August 2017, was marked for identification, as of this date.)
BY MR. FAES:
Q. Can you tell me what that is?
A. That is an invoice for the hours spent on creating and finalizing this expert report. It doesn't include the hours also spent preparing for this deposition.
Q. So this would include all of the hours that were spent creating your Prolift expert report that's dated August 16th of 2017, right?
MS. KABBASH: The date's likely on the back.
A. Correct.
Q. Approximately how many hours would you say that you spent preparing for your deposition here today?
A. Probably an additional eight to ten hours.

Q. And how many days did you spend?
A. Three.
Q. Was that all with counsel, or was some of that on your own?
A. Some of that was on my own. Approximately three hours was with counsel.
Q. Other than the flash drive marked as Exhibit Number 5 and the invoice marked as Exhibit Number 6, have you brought any other documents or things with you here today in response to the document requests in the notice?
A. No.
Q. I'm going to hand you what's been marked as Exhibit Number 2 to your deposition.
(Wagner Exhibit 2, Expert Report of John R. Wagner, M.D., dated August 16, 2017, was marked for identification, as of this date.)
BY MR. FAES:
Q. I think you've already got a copy of it in front of you.

Can you tell me what that is?
A. This is my expert report.
MR. FAES: Do you need a copy, Maha?
MS. KABBASH: I have one.
BY MR. FAES:
Q. This report is signed and dated August 16th of 2017; is that right?
A. Correct.
Q. Does this report contain all the opinions that you've reached regarding the Prolift product?
A. Yes.
Q. Now, the title of this report on page 1 is "Gynecare Gynemesh PS Prolift and Prolift+M."
Do you see that?
A. I do.
Q. Is it your understanding at this time that you've only been declared as a general expert on the Prolift product?
A. That is my understanding.
MR. FAES: And just for the record, counsel, is that correct, he's

only been declared at this point as a general expert on the Prolift product?
MS. KABBASH: That's correct. He's only had the Prolift portion of his general report designated in Wave 6 so far.
MR. FAES: Okay. I just wanted to make sure that that's why we're only doing the two hours today and that if he were to be designated on the Prolift+M or the Gynemesh PS at some future point that we may ask to re-depose him on those products.
Fair enough?
MS. KABBASH: That's my understanding.
MR. FAES: Okay.
BY MR. FAES:
Q. Now, Doctor, there are various articles cited through your expert report marked as Exhibit Number 2, correct?
A. Yes, there are.
Q. In terms of your decision-making and writing the report, why did you decide

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to cite the articles that you did?
A. I decided to cite the articles that I felt best represented the opinion I was trying to make at that point in the report.
Q. And in terms of gathering the articles that you reviewed and relied on for your report, what was your process for that?
A. My process was to look at the articles that I maintained myself. Most of the articles that I maintain, with a few exceptions, are from the American Journal of Obstetrics and Gynecology, the OB-GYN Green Journal, the Journal of Minimally Invasive Gynecology, the Journal of Female Pelvic Medicine and Surgery, and then I have a few articles that I maintain in my library that I've secured from more international journals.
And then beyond that was added by counsel and providing more international journal citations that would support the opinions that I was setting

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forth.
Q. Did counsel provide you any journals that didn't support the opinions you set forth in the report?
A. There were citations from, let's say, Clave talking about mesh properties that comes from the international journal that don't support the opinions that I put forth. There was citations from Otto in 2003 that don't support the opinions that I put forth. But I also provided opinions from other sources and citations to refute those studies.
So yes, I was provided with studies that don't support my opinions necessarily, and I actually have some articles, particularly from Cheryl Iglesias, in my own library that don't necessarily support the opinions that I put forth here.
Q. So, in terms of writing your report and forming your opinions, did you ever go out and try to find the materials and literature out there that didn't

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support the opinions that you're offering in this case, as well as find materials that did support the opinions?
A. I think in my --
MS. KABBASH: Objection to form.
A. I think in my role as a pelvic surgeon, I'm always looking to read anything that I can about the subject, and sometimes those articles, particularly if they're good quality, will change my opinion one way or the other. So as a function of what I do, I'm always looking for more information and more up-to-date information and the highest quality data that I can get to -- to do the best job that I could do in terms of clinically treating my patients.
Q. So, in terms of materials that didn't support some of the opinions that you're offering in this case, you specifically mentioned the Clave study, right?
A. Yes, I did.
Q. So you'd agree with me that

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there are articles out there in the peer-reviewed literature that do not support your opinion that polypropylene mesh does not degrade, correct?
A. I think that article is one. I'm not sure that I would agree with the concept that there's articles. Certainly there's not an abundance. I think the vast majority of peer-reviewed literature, particularly from the major medical journals, as well as the opinions from major medical societies like AUGS and SUFU, don't agree with Clave and his conclusions. So, I think there's a vast amount of literature that doesn't support his opinions, and it's a vast amount of opinion from medical societies that I subscribe to and respect that don't support his opinions.
Q. And one of the other articles that you mentioned is the Iglesias article, correct?
A. Yeah. I don't know if I can quote an article on her, but I have some

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articles. She tends to be somebody that I read who doesn't necessarily support the use of mesh in some of the cases where I believe it should be used. I think she's not as supportive of mesh implants in general transvaginally, as a lot of opinion leaders are. So I think that it provides me with a balance.
Q. But you'd agree with me that there are articles out there in the peer-reviewed medical literature that don't support the opinion that the Prolift device is safe and effective, correct?
A. Again, I don't agree with the statement the way you worded that. I have trouble with that.
Q. So you think that all of the medical literature in the --
MR. FAES: Strike that.
Q. So you believe that all of the peer-reviewed medical literature that studied the Prolift device supports your position that it's safe and effective?
MS. KABBASH: Objection.

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BY MR. FAES:
Q. Is that your opinion?
MS. KABBASH: Objection to form.
A. No, I don't agree with that statement either.
Q. I'm going a little bit out of order, but I want to hit it and we'll get into it a little bit later. We talked a little bit about articles on degradation, and obviously you've been deposed before and testified extensively on that issue, right?
A. I've been deposed before, and I -- I have testified on one pelvic mesh case as a expert witness for Ethicon. I don't know if that counts as extensive. I think I'm a -- would still consider myself a relative novice at this.
Q. So, would you say that your opinion regarding polypropylene mesh is that it doesn't degrade at all or that it may degrade, but if it does, it's not clinically significant?
A. It is my opinion that

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polypropylene mesh is inert and does not degrade.
Q. Okay. Now, in your report marked as Exhibit Number 2, you also go through various facts and you discuss facts, right?
A. Yes.
Q. Did you discuss the facts in your report that you felt were most important to you in drawing your opinions in this case?
A. Yes, I tried to.
Q. You've also got a reliance list in this case, right?
A. Yes.
MR. FAES: And I'll mark that as Exhibit Number 3 to your deposition.
(Wagner Exhibit 3, John Wagner General Reliance List in Addition to Materials Referenced in Report MDL Wave 6, was marked for identification, as of this date.)
BY MR. FAES:
Q. I'll give you a copy of that

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(handing.)
Actually, let me back up a little bit because I forgot to ask you a question about your report.
Did you write your entire report marked as Exhibit Number 2 on your own?
A. Not the entire report, no.
Q. So, there are portions of the report marked as Exhibit Number 2 that you didn't write on your own?
A. There were portions of that report where the -- with the aid of counsel, counsel skeletonized some of it and I helped fill in the body of the report.
And, I should say that the opinions in the report are all mine and that I had complete control over the contents of that report. I had total editorial control over that report.
Q. But it's fair to say that you were provided with a skeleton or outline which suggested what your potential conclusions may be?

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A. No.
MS. KABBASH: Objection.
A. That is not fair. I would say that significant part of that report was taken verbatim from my previous TVT report, certainly the introductory portions, and that was completely written by myself.
There are the opinion portions of the report are really generated from my own words and Dictaphone.
The skeletonizing that counsel provided me with was primarily in summarizing just conclusions of some of the studies that I wanted to cite, but the opinions in there are completely my own.
Q. Is there any way for me to tell which portions of this report were actually not written by you?
MS. KABBASH: Andy, I'm just going to state an objection and instruct Dr. Wagner not to answer any questions that seek specifics regarding what was written by him or

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not, beyond what he's already testified to, based on the fact that it violates the federal civil rules.
MR. FAES: Okay. Let me withdraw that question and ask a new one.
BY MR. FAES:
Q. This quality of evidence pyramid on page 18 of your report.
A. Yes.
Q. This is --
MR. FAES: Well, strike that. He's already answered that. I don't need to ask him again.
Q. Going back to your reliance list, Doctor.
This reliance list marked as Exhibit Number 3, who prepared this reliance list?
A. Counsel prepared this reliance list.
Q. Does this reliance list marked as Exhibit Number 3 contain all of the materials you reviewed and relied upon in

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forming your opinions in this case regarding the Prolift?
A. Yes.
Q. And is this reliance list the same reliance list as you used for your most recent TVT report?
A. It includes more studies than my most recent TVT report 'cause it includes studies that involve Prolift which were not included in the TVT report.
Q. In forming your opinions regarding the Prolift, do you rely on midurethral slings in the TVT to form any of your opinions regarding the safety and efficacy of the Prolift?
A. I think there are parts of my Prolift report that do rely on some of the literature from TVT, particularly as it relates to issues of so-called contraction of the mesh. In my report I refer to TVT in that regard. There are other parts of the report that talk about mesh properties in general that I overlap with the TVT and use the TVT as part of my supporting

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literature.
Q. And have you reviewed all of the materials that are listed in Exhibit 3, which is your reliance list?
A. I believe I've tried. I think that some of the mesh studies are studies that I have just superficially reviewed, but I've tried to review all of the studies.
I think the things that I haven't reviewed are some of the Ethicon internal documents. I haven't some of those, but I tried to reviewed everything that counsel sent to me, at least to be able to say that yes, I have reviewed it, some that I find more important than others.
Q. So if I heard you correctly, there's at least some internal documents listed on Exhibit Number 3 that you haven't actually reviewed; is that correct?
A. It's hard for me to say because I've tried to review everything, but if I

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had to provide you with the most accurate opinion, I think there's probably some internal documents here that I have not seen. Although I have to say I made a legitimate effort to try to review everything that they sent to me.

Q. And there's also two pages of company witness depositions on your reliance list.

A. Yes.

Q. Have you reviewed all of the company witness depositions on your reliance list?

A. I'd have to give this -- I'd have to give the same answer because I was sort of lumping that together. But I have reviewed testimony from Piet Hinoul. I've reviewed testimony from Dr. Weissberg.

So again, I can't say that I reviewed all of the testimony, but I have made an effort to review part of it.

Q. So it's fair to say that there is some deposition testimony listed on your reliance list that you haven't

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actually reviewed, right?

A. I think that's probably a fair statement, yes.

Q. As you sit here today, do you have any type of list that you could provide that would give us all of the deposition testimony and internal documents that you have actually reviewed?

A. That would be hard because I believe that counsel sent me everything that is on this list. So if -- it would be very hard for me to say yes, I looked at that and I didn't look at this. It's very hard for me to separate out those two.

I tried to read this when it's provided to me and try to read the literature when it's provided to me. I just don't think I've read all the deposition testimony. And I don't believe I've read all of the internal documents. I do believe I've tried to read all of the articles that are provided to me.

Q. For example, on your reliance

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list on the first page of the company witness materials there's two depositions for Thomas Barbolt.

Do you know who that is?

A. Could you refer me to the page again? I'm sorry.

Q. Well, if they had page numbers, I could.

MR. FAES: I think counsel deliberately did that.

MS. KABBASH: Off the record.

(Discussion held off the record.)

A. So, these two references to Thomas Barbolt, I don't know that I have or have not read that deposition testimony.

I have read deposition testimony for Arnaud above there, Piet Hinoul. I just don't know if I've read anything by, is it Barbolt?

Q. Yes.

A. I don't know if I have or not. I can't give a yes or no to that.

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Q. Do you remember being asked questions about Dr. Barbolt's testimony at your Adkins deposition?

A. No, I don't think that I do. Although I could have. I don't remember it.

Q. So it's fair to say that you don't -- you didn't make any effort after your Adkins deposition to go back and review his testimony to see what he -- who he was and what he might have testified about with regards to Thomas Barbolt?

MS. KABBASH: Objection; asked and answered.

A. Yeah, I'm not sure I understand the question.

When you referred to "he," are you referring to Thomas Barbolt?

Q. Yes.

MR. FAES: Let me restate the question.

BY MR. FAES:

Q. Is it fair to say that after your testimony in the Adkins deposition,

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you didn't go back afterwards and review Dr. Barbolt's deposition to see who Dr. Barbolt was and what he testified about?
A. What I testified about or what he testified?
Q. No, what Dr. Barbolt testified about.
A. I don't recall doing that.
Q. Okay. Are you aware of whether or not Dr. Barbolt was in fact a company designated witness, a person who was designated to testify on behalf of the company regarding certain matters?
A. I don't recall. If I ever was aware, I don't remember it.
Q. Doctor, I'm going to hand you what's been marked as Exhibit Number 4 to your deposition.
(Wagner Exhibit 4, Curriculum Vitae of John R. Wagner, M.D., was marked for identification, as of this date.)
BY MR. FAES:
Q. That's just your CV, right?

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A. Correct.
Q. Have there been any changes to the CV since your last deposition in March of this year?
A. I don't think so.
Q. Is the typo still in there?
A. It probably is.
Q. Now, Doctor, you've actually published an abstract or article on the Gynemesh PS mesh in the past, right?
A. I have.
Q. And you know that the Gynemesh PS mesh is the same mesh that's used in the Prolift device, right?
A. Correct.
Although I should correct my previous answer because you said "published." I don't think I published it. It was presented at an ACOG meeting in 2006, I think.
Q. And in that presentation of the study that you did on 33 Gynemesh PS patients, you followed those patients for up to one year, right?

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A. Yes. I have to go back and look exactly, but that's my recollection is about that time frame.
Q. Did you follow those patients beyond that time?
A. I'm certain that I did because they were my patients. I don't think they were really patients that were referred to me at the time and I'm certain that I did, but I did not follow them in an organized manner. I did not continue the study beyond that period.
Q. At that one-year follow-up, you found that 8 of the 33 patients, or 15 percent, had an erosion or extrusion of mesh of some kind during that follow-up, right?
A. Yes, that number seems correct to me.
Q. Just in case you need to refer to it, I'm going to mark that article as Exhibit Number 7 to your deposition.
(Wagner Exhibit 7, April 2006 Wagner article "Vaginal Repair of

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Symptomatic Pelvic Organ Prolapse Using Polypropylene Mesh, was marked for identification, as of this date.)
BY MR. FAES:
Q. Doctor, do you intend to offer any opinions in this case on what you feel the overall erosion, extrusion, and exposure rate of the Prolift mesh is in patients?
A. I think that I can offer an opinion based on my experience over the last 12 years, as well as the reported experience from others in the peer-reviewed literature.
Q. And what is the opinion that you intend to offer?
A. That the mesh erosion rate, and I'm going to include every type of visible mesh in that heading, is probably on the order of about 2 to 5 percent in general. And there's variation in that based on, I think, in my opinion, surgical experience and variation in that as procedures have been modified over the years.

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Q. So, you believe, I just want to make sure I have your opinion, that I understand your opinion correctly. You believe that the overall combined erosion, exposure, and extrusion rate for the Prolift mesh is between 2 and 5 percent?
A. I think in well-designed studies by experienced surgeons who are experienced with the device that that is roughly my opinion, correct.
Q. And is your opinion the same with regard to the Gynemesh PS mesh, or do you have an opinion?
A. The Gynemesh PS that I was using in 2006 were basically mesh patches that I placed after performing a repair. It's the same mesh, but the technique is different. And with Gynemesh PS, it's just a blank sheet of mesh that can be used with different techniques.
So I'm not sure that I can apply a mesh erosion, extrusion, or visible mesh rate to the use of the mesh. I think the rate applies more towards how it's used

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and by whom.
Q. So, I'm not sure if I understood your opinion or not.
Do you have an opinion regarding the overall mesh erosion, exposure, and extrusion rate of the Gynemesh PS mesh, which is the mesh used in the Prolift, or not?
A. I think let me restate my answer to that maybe more clearly.
I think that the mesh itself is just a sheet of mesh. It can be applied in different ways, cut different ways, placed different ways through different incisions by different surgeons for different defects, and I think all those factors would affect the rate of mesh erosion.
And so, as a result, I don't know if I can give you a specific number that reflects just the mesh because it's modified by all those other factors.
Q. Okay. So it's fair to say that you don't intend to offer an opinion in

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this case regarding the overall mesh erosion, exposure and extrusion rate of the Gynemesh PS mesh specifically, correct?
MS. KABBASH: Objection.
A. I have to go back on what I just said. I don't think I can give you an opinion regarding the mesh itself and erosion rate because there's too many other factors that go into that.
Q. Okay. But your opinion regarding the Prolift mesh is that it has an erosion, exposure, and extrusion rate of between 2 and 5 percent despite the fact that your own personal experience in 33 patients using the same mesh in the Prolift showed a 15 percent erosion, exposure, and extrusion rate, right?
MS. KABBASH: Objection to form.
A. I think you're dealing with apples and oranges here because the mesh is the same, but all the other factors that I stated affect the erosion rate.
And I think that if you look at

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from a overall perspective the history of mesh implants in the vagina, that our initial erosion rates for almost everybody were higher when we first started and lower as time went on because we all learned techniques to minimize the risk of erosions, whether it was not performing hysterectomies, avoiding T-incisions, making smaller incisions, doing different dissections. We all have developed techniques to minimize erosion rates.
So, erosion rates in 2004, in my opinion, are really not the same as they are in 2014. And to specifically compare Gynemesh, which is just a blank sheet of mesh that can be altered and placed in many different ways and altered in many different ways to a specific procedure like the Prolift, I don't think is accurate. It's not -- it's not accurate.
Q. So I --
A. I don't think you can compare those two erosion rates.
Q. Right, I understand that you

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don't think it's apples -- that you think it's different, it's apples and oranges, but if you could, Doctor, please just focus on the question that I'm asking.

My question was you believe that the overall erosion, exposure, and extrusion rate of the Prolift mesh is between 2 and 5 percent, and you believe that despite the fact that your own experience with the mesh in the Prolift, the Gynemesh PS, was 15 percent in 33 patients that you followed.

Is that statement correct?

MS. KABBASH: Objection.

A. Yeah, it's correct based on my experience with the Prolift, my clinical experience with the Prolift and the published studies and peer-reviewed literature consistent with the Prolift. So the literature supporting the Prolift supports that number. My experience with the Prolift supports that number.

Q. When is the last time you used the Gynemesh PS mesh in your clinical

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practice?

A. I think 2005 or 6.

Q. And when is the last time that you used the Prolift mesh in your clinical practice?

A. Probably one or two months after Gynecare stopped producing it.

Q. It's fair to say that the last time that you used the pelvic mesh was in 2012, right?

A. I think it was probably 2012, mid-2012.

Q. And you understand that the Gynemesh PS mesh is still available by Ethicon for the treatment of pelvic organ prolapse, right?

A. Yes.

Q. But you, despite it being available, you have opted to use the Coloplast Restorelle mesh as your mesh of choice for the treatment of pelvic organ prolapse, right?

A. I migrated to using that one primarily because I was using their

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trocar-based vaginal mesh repair system, and buying their products was my hospital's choice.

Q. Which trocar-based vaginal mesh system are you referring to? Is it the Exair, Novasilk?

A. Yes.

MS. KABBASH: He couldn't remember.

A. I could not remember the name of it, but it was the Exair. So when the Prolift was removed, I migrated to the Exair because I liked the trocar-based approach and I used that, and for reasons that have to do with hospital purchasing, we migrated to the Coloplast products. But I've used Restorelle. I've used Alyte mesh.

I really think that almost all the meshes -- let me rephrase that.

I think that all the meshes that are available for sacrocolpopexy on the U.S. market now are pretty much interchangeable. They're all -- they are

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all large pore, lightweight meshes.

Q. Did I hear you say that you used the Alyte mesh?

A. I did. I do.

Q. And do you still use that currently?

A. I think my primary mesh is probably still Restorelle, but I do use the Alyte. I think it also has to do with which hospital I'm operating at.

But as I said before, I think the meshes available for sacrocolpopexy on the U.S. market are all interchangeable.

Q. And the Alyte mesh is, you're referring to the Y-mesh manufactured by Ethicon and Johnson and Johnson, right?

A. Yes.

Q. And are you aware of whether or not the Alyte mesh uses the same mesh that was utilized in the Prolift+M?

A. Not aware.

Q. Do you know whether or not the Restorelle mesh is in fact half the weight of the Gynemesh PS mesh?

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A. Again, I consider them all large pore, lightweight meshes.
Q. That wasn't my question though.
My question was do you know whether or not the Restorelle mesh made by Coloplast is in fact half the weight of the Gynemesh PS mesh or not?
A. I'm not aware because I find it clinically insignificant. So it would not be a fact that I would be aware of. They're all large pore, lightweight.
Q. So, the last time that you used the Gynemesh PS mesh was in 2005 or 2006, right?
A. I believe so. I can't say that I've never, ever used it since, but if it -- if I did, it was only once or twice.
Q. Why did you stop using the Gynemesh PS mesh for the repair of pelvic organ prolapse?
A. Because the Prolift system came on the market.
Q. And the last time you used the Prolift mesh was in 2012, right?

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A. Correct.
Q. And why did you stop using the Prolift mesh for the treatment of pelvic organ prolapse?
A. Because Gynecare removed it from the market.
Q. When the Prolift device was no longer in the market, what product did you go to for the treatment of pelvic organ prolapse? What did you start using at that point?
A. I'm not sure what I used initially for the first few months, but I quickly migrated to using the Exair trocar-based system from Coloplast.
Q. Why did you migrate to using the Exair system as opposed to going back to the Gynemesh PS mesh?
A. Because the trocar system I felt, and still feel, provides the best option for treating pelvic prolapse.
And additionally, even without a trocar-based system, I wouldn't migrate back to the Gynemesh because it's not

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pre-cut. So if I use a mesh implant that's not trocar-based now, I use the ones that are pre-cut and formed to fit whatever vaginal compartment I'm repairing. Whereas the Gynemesh PS is just a blank sheet.
So, for two reasons I didn't go back to the Gynecare -- Gynemesh PS. The first reason was I wasn't going to use a trocar-based system, I was going to use a pre-cut mesh, and the second reason is I prefer a trocar-based system than the Gynemesh PS.
Q. So, in your expert report on page 12 you state that the Gynemesh PS is a low-weight mesh.
Is that an opinion you tend to offer in this case?
A. Yes.
Q. What standard are you applying for your opinion in this case that the Gynemesh PS is a low-weight mesh?
A. The polypropylene mesh properties that I'm most interested in are

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the pore size and its overall just sort of weight. Feel is a good term, is how I would put it. And most important is the pore size. And this has a light feel and a large pore size.
Q. Right, but my question is very specific.
My question is what standard are you applying for your opinion in this case that the Gynemesh PS mesh, which is the same mesh that's in the Prolift, is low-weight?
A. Just that the overall volume of polypropylene is small. It's a large weave, large pore mesh.
Q. So, you're not applying any objective standard for your opinion in this case that the Gynemesh PS mesh is a low-weight mesh; is that accurate?
MS. KABBASH: Objection.
A. I'm applying a clinical standard based on my experience with my patients, and I'm applying a standard that's reflected in the medical literature on the

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repair of these patients, and in the peer-review literature, these are considered low-weight meshes.

The exact standard, I don't know if I could cite you that as I could with pore size, such as the Amid classification on pore size, but the medical literature in the peer review journals that talks about the various meshes considers these to be low-weight meshes.

Q. Are you familiar with the Cobb Heniford study?

A. Without looking at it, I'm not sure that I could tell you that I'm familiar with it.

If you have a copy of it, I'd be happy to look at it and see if it jogs my memory.

Q. Are you familiar with the fact the Cobb Heniford study states that in order for a weight to be considered lightweight, it needs to be 35 grams per meters squared or less, right? Or are you aware of that?

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MS. KABBASH: Objection.

A. I'm not aware of that study and that standard.

Q. So, are you aware of the standards that the Achen [ph] Group came out with with regard to whether or not a weight is lightweight or not?

A. I am not aware, as I sit here, without looking at something that you might give me to trigger my memory on that, no.

Q. Can you cite to me any specific article or journal that states that a mesh that is 45 grams per meter squared is considered a lightweight mesh?

A. I think that the large volume of literature that's just out there on mesh repairs vaginally considers that to be a lightweight mesh. I don't find any literature in my peer review journals or elsewhere that refers to polypropylene mesh, such as Gynemesh or what's in Prolift, to be considered anything more than low-weight.

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Q. But as you sit here today, you can't cite or name any specific article that specifically says that a mesh that is 44 grams per meter squared like the Gynemesh PS is a low-weight mesh?

A. I'm certain that I could go through my reliance list and the articles that I've cited in here and come up with phrases talking about low-weight mesh being consistent with Gynemesh PS.

Q. So, what is your threshold in terms of grams per meter squared between what's -- what's the cutoff for a low-weight mesh, or do you have an objective number in mind that's a cutoff?

A. I don't really have an objective number in mind. I think that the -- again, I go back to the volume of literature that's out there talking about low-weight meshes.

And I don't recall a specific reference like we have with pore size and Amid. I don't recall specific reference to that. Just that the entire body of

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literature that is in my journals refers to this as a low-weight mesh.

Q. So in your mind, there's no maximum number to be applied where you say the weight has to be this number or below in order for it to be a low-weight mesh; is that correct?

A. No, I don't have an absolute number.

Q. Would you agree that Ethicon and Johnson and Johnson has not launched a mesh for the repair of pelvic organ prolapse that's heavier than 45 grams per meter squared --

MR. FAES: Well, strike that.

Q. Would you agree with me that Ethicon has not launched a mesh that is heavier than the Gynemesh PS mesh since it was launched in 2002?

A. I don't think they have. And my only hesitation there is I'm not familiar with all the products out there for the general surgery mesh repairs and hernia repairs. But certainly in gynecology they

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haven't launched a product that has a higher grams per meter squared number.
Q. Would you agree with me that Ethicon and Johnson and Johnson doesn't sell a mesh that's indicated for transvaginal repair of pelvic organ prolapse that's as heavy as the Gynemesh PS or Prolift mesh?
MS. KABBASH: Currently you mean?
MR. FAES: Yes.
A. There's two questions in that question. The first is Gynecare Johnson and Johnson doesn't market a mesh at all for transvaginal mesh repairs, that I'm aware of. And they also -- so right there, I think that ends the question. And then because whatever weight after that would be irrelevant.
Q. So you'd agree that Ethicon and Johnson and Johnson currently doesn't market a mesh for the transvaginal repair of pelvic organ prolapse, correct?
A. Correct.

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Q. And you'd agree with me that the Gynemesh PS is no longer indicated for the transvaginal repair of pelvic organ prolapse, correct?
A. It is not approved by the FDA for transvaginal mesh repair. It's approved for transabdominal, but I have to quantify that by saying that we use a lot of drugs and devices for indications that the FDA doesn't approve them for.
For example, every drug we use to treat premature labor is not approved as a premature labor drug, and the only drug that is approved for premature labor is ritodrine, which hasn't been used in about 25 or 30 years. So, FDA approval for use doesn't translate into clinical use in the hands of doctors with good peer review studies.
So, this is sort of a long-winded way of saying that the FDA's approval is for transabdominal use, but that doesn't mean it could not be indicated for transvaginal use in the

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hands of a clinician with good supporting data and experience in the proper indication.
Q. The Gynemesh PS has an IFU, or instructions for use, that includes indications, correct?
A. It would include indications. It would include FDA approved indications. Again, I go back to my analogy with the drugs that we use to treat preterm labor. They have indications, but they're not preterm labor, but once they're on the market for one use, if there's good clinical data and experience using them for other uses, we can use them for those purposes.
Q. And you'd agree with me that the IFU, or instructions for use, for the Gynemesh PS currently does not have an indication for transvaginal use, correct?
A. It's not FDA approved for transvaginal use.
Q. I'm not asking about FDA approval. I'm just asking you what's in

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the instructions for use for the Gynemesh PS.
A. Well, I'm sure --
Q. The Gynemesh PS IFU currently does not have an indication for transvaginal implantation, yes or no?
A. It does not have an indication per its IFU. But again, I qualify that answer by saying that there are lots of things that aren't indicated that are used for purposes than what they originally were approved for by the FDA, and because of the laws, the company can't indicate that.
Q. So, on page 16 of your report you state that: "Abdominal operation to say repair pelvic organ prolapse such as sacrocolpopexy have been associated with higher morbidity compared to vaginal procedures."
Do you see that?
A. Yes, I do see that.
Q. Is that an opinion that you intend to offer in this case?

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A. Yes.
Q. What do you mean by "higher morbidity"?
A. Abdominal procedures historically are associated with an increase risk of complications overall compared to vaginal procedures. The higher morbidity refers to additional complications that occur at a higher rate with abdominal surgery, which is bowel ileus, bowel complications, bowel injuries, prolonged recoveries, increased pain translates to increased risk for pulmonary complications, thromboembolic complications. Historically, vaginal surgery has a lower morbidity associated with it than abdominal surgery.
Q. Would you agree with me that in general in someone who requires a mesh implant, a surgeon would probably prefer to place it abdominally because the complication rate is probably lower?
MS. KABBASH: Objection to form.
A. I can't agree with that

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statement as a blanket statement. There's way too many caveats with that. It depends on the patient's ability to withstand either open surgery or if you perform it minimally invasively their ability to withstand three hours in Trendelenburg position. They may have medical comorbidity that does not allow that that would make that unsafe. And then there are vaginal mesh repairs in that patient that would be far less morbid and have a far lower complication rate than the transabdominal approach.
So as a blanket statement, I don't think I can agree with that at all.
Q. So you don't agree with that statement; is that correct?
A. Not the way it was phrased, no.
Q. Do you remember testifying earlier this year that in general it would be your current thinking in someone that requires a mesh implant we would probably prefer to place it abdominally because the complication rate is probably lower?

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A. I think that statement with the caveats that I just gave you is absolutely true. If there are patients who we lean more towards doing abdominally and there are patients we lean more towards doing vaginally. In a perfectly healthy patient, with the advent of minimally invasive techniques, robotic, laparoscopic techniques, I would probably prefer to place the mesh abdominally than vaginally, but there are clearly indications in situations where a vaginal mesh repair would be less risky.
So, there are times when I do vaginal mesh repairs today. There are times when I do abdominal mesh repairs today. But in general, I would say that over the last ten years, I do more abdominal mesh repairs because we can do them minimally invasively than I used to in the past.
Q. So you'd agree that in a perfectly healthy patient it's, in general, your thinking that in a person

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who requires a mesh implant, you would generally prefer to place it abdominally because the complication rate is probably lower?
MS. KABBASH: Objection.
A. Yes. In a perfectly healthy patient without contraindications to surgery, that would make the abdominal procedure more morbid.
Q. And just to follow up on your previous answer.
Did you say that there are still patients that you place mesh transvaginally in today?
A. Absolutely.
Q. What mesh do you use for transvaginal -- for a transvaginal placement when you do it that way?
Probably a terrible question.
MS. KABBASH: Objection.
A. Currently, without the Exair, I've been using the Coloplast anterior and posterior mesh implants and they are sutured in place. I've occasionally used

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the Uphold, but there are hospital issues that make it a lot easier to use the Coloplast product, so I tend to use those products when I do vaginal mesh repairs.
Q. So, do you use the Restorelle L or the Restorelle Flat Sheet for that?
A. I'm not sure exactly the name of it. I think it is Restorelle anterior or Restorelle posterior, but I can't -- I can't actually say I know the product name, per se.
Q. When was the last time you put in an Exair?
A. Just a week or two ago.
Q. Is the Exair still available?
A. Sorry, I misunderstood your question.
I have not put in an Exair for a while. I thought we were talking about the Coloplast anterior repair.
I haven't used the Exair since Coloplast removed it from the market when the FDA switched it from a class II to a class III device.

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Q. So that was in 2016 some time?
A. Roughly, yes.
Q. Would you agree with me that there are currently no trocar-based mesh implantation systems available for the treatment of pelvic organ prolapse, correct?
A. I would agree with you. At least not in this country.
Q. Would you agree with me that if a patient requires a very large mesh implant of the anterior --
MR. FAES: Well, strike that.
Q. Would you agree with me that if a patient requires very large transvaginal mesh implant, you would prefer to place it abdominally if that person is a candidate for surgery?
A. I -- I don't think that it's as much the size of the defect as it is the patient's candidacy for an abdominal operation. The abdominal operations require specific positioning. They require much longer anesthesia. And

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they -- there are patients who have other comorbidities, such as diverticulitis and diverticulosis and abdominal adhesions that make the abdominal approach not the wisest. And I don't think the size of the vaginal defect is as important to me as is the patient's ability to withstand the abdominal operation.
MR. FAES: Let me see if I can rephrase the question.
Q. Would you agree with me that if a patient requires a very large mesh implant for the treatment of pelvic organ prolapse, you would prefer to place it abdominally if that patient is a candidate for abdominal surgery?
A. Again, I think that I go back to what I just answered.
To me, it's not as much the size of the defect as the candidacy for abdominal surgery. That trumps the size of the defect. If that patient had a very large vaginal defect, but was not a candidate for abdominal surgery, then I

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would place the mesh vaginally.
Q. How often would you say you excise or implant --
MR. FAES: Strike that.
Q. How often would you say that you excise or explant transvaginal mesh in a typical year?
MS. KABBASH: Prolapse only or are you including slings?
MR. FAES: First let's go with any kind of transvaginal mesh, including slings or -- so let me restate the question, since there's a counsel objection, or I don't know if that was an objection.
MS. KABBASH: Request for clarification.
MR. FAES: Yes.
BY MR. FAES:
Q. Doctor, how many times per year would you say you explant a polypropylene mesh from a patient, including prolapse mesh and stress urinary incontinence mesh?
A. At this point, not very often.

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I would say that probably about twice a year under anesthesia, maybe once or twice a year in the office setting, but not very often. And actually, I don't remember the last time that I really explanted a piece of mesh from a vaginal mesh repair. It has to be over a year ago probably. The recent explants are usually more TVT slings.

Now, earlier on, if you go back ten years, I was doing it much more frequently. So I think that reflects what I sort of alluded to before, which is that as experience with transvaginal mesh repairs developed, we developed techniques surgically to minimize the risk of erosions, and that's minimized then the number of mesh explants that have been necessary. So my surgical rate ten years ago was much greater than it is now.

Q. Would you agree with me that there are currently no products on the general market in the United States for the treatment of pelvic organ prolapse

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that include a mesh arms like Prolift?

A. Yes, I would agree with that in the United States. I don't know about elsewhere.

Q. And you used the Prosima 20 to 30 times to treat pelvic organ prolapse, correct?

A. I did.

Q. And you understood that that device utilized the Gynemesh PS mesh, which is the same mesh that's in the Prolift device, correct?

A. Correct.

Q. And the Prosima device does not include the use of mesh arms, correct?

A. That is correct.

Q. When you first started using the Prosima device, was that sold or explained to you as a potential benefit of the Prosima device, the fact that it didn't use arms or didn't include the use of mesh arms?

A. It was, quote, sold to me, end quote, as just being different. I don't

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know if it was good or bad. And you could make an argument that by not placing trocars through the obturator foramen that that required less surgical dissection and intervention which would translate into less risk. But one could also argue that the lack of the arms would lend itself towards a higher prolapse recurrence risk and potentially increase the risk for future surgery for a failed repair.

So, I think that it was, at least in my opinion, marketed to me as something different that might have a place in our armamentarium of mesh products, but not as necessarily obviously better.

Q. So you'd agree with me that a mesh device that doesn't require the passage of trocars through the obturator foramen may have potential safety benefits due to the lack of those passes, correct?

A. Correct, I agree with that, but that's just an isolated factor as one part of the procedure. But I think that not

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passing the trocars eliminates any potential risk of trocar-related injury.

Q. Do you still, for the treatment of pelvic organ prolapse, do you still do native tissue repairs with sutures, or are all of your repairs with mesh?

A. No, I still do native tissue repairs.

Q. In what situations do you do native tissue repairs with sutures as opposed to using a mesh?

A. If somebody has an isolated defect in the vagina, just an isolated cystocele or rectocele with good support otherwise, I will certainly consider doing a native tissue repair.

I think the one time that I will always, 99.9 percent of the time use mesh is with midurethral slings. I think the role for native tissue repairs to treat incontinence is very, very limited, close to nonexistent. And I think that I will do native tissue repairs of uterine prolapse when I can palpate the ligaments

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holding the uterus up and use them to support the vaginal cuff.
Q. When you did the Prolift procedure, did you view native tissue repairs with sutures as an alternative to the Prolift and vice versa?
A. Yes.
Q. In terms of alternative treatments for a patient, abdominal sacrocolpopexy would be one of the alternatives if in fact there were prolapse in that part of the pelvis that would be appropriate for treatment, right?
A. Yes.
Q. Just for the rest of the day I'll probably use ASC for abdominal sacrocolpopexy because I can't pronounce it. It's a tongue twister.
A. It will make it actually easier for me if you do.
Q. Other than the Exair and the Prolift and the Prolift+M and the Prosima, what other kits have you used for the treatment of pelvic organ prolapse?

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A. I have used the Uphold kit. I have at least once or twice used Apogee and Perigee very early on, which were the AMS products. And as I said, I currently use the Coloplast anterior and posterior mesh implants.
Q. And the Alyte, I forgot that.
A. And the Alyte. Thank you.
Q. Anything else that you used?
A. I think that's it.
Q. Have you ever used the Elevate kit?
A. Yes, I have used the Elevate kit, very briefly. I would venture to say maybe five to ten times, and if I had to guess when, I would say like 2008 to 2010, maybe in that range.
Q. Do you recall that like the Prosima, the Elevate doesn't have trocar passes?
A. I do recall that.
Q. You would agree with me that that's one significant difference between the Elevate and the Prolift is that the

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Elevate doesn't have trocar passes, correct?
A. Yes, that's one difference.
Q. The fact that there were no external trocar passes with the Elevate, did you see that as a potential benefit from a safety perspective as compared to the Prolift?
A. No, because safety to me is defined by more than just the trocars. Safety to me is defined by the -- the extent of the dissection, the extent of mobilization of the bladder. Safety to me is defined as avoiding bunching of the mesh, placing the mesh on an appropriate level of tension.
So it, in a way, the trocar-based systems allowed you to place the mesh in a minimally invasive way through small incisions with less dissection, and they were the only systems out there that allowed you to place the mesh on an appropriate level of tension to minimize complications related to

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overtightening, and the benefits in that regard outweighed the risk of the trocar insertions which were, in my hands and in the hands of other surgeons in the literature, very minimal. The risk of injury was quite small.
So that overall safety profile of the trocar-based procedure, Prolift and then Exair, but particularly Prolift which was my primary repair, was much better using a trocar-based system than not using a trocar-based system.
Q. You'd agree with me that one of the risks of external trocar passes with the Prolift is that nerves could be damaged, correct?
A. I would agree with you that any pelvic operation could injure pelvic nerves. Doesn't have to be trocar-based. And quite frankly, you could say that the risk of not using a trocar requires more extensive dissection that might interfere with more, let's say, nerves to the bladder and result in more bladder

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dysfunction than not using a trocar.
So, it's a different entity. I mean, surgery can increase the risk to nerves. The more extensive the surgery, the more potential risks to nerves, blood vessels and other structures. The less extensive surgery, the less risk to those structures.
And to me, the Prolift trocars and the trocar-based systems offered an opportunity to do less invasive surgery.
Q. My question is very specific though.
My question is one of the risks of the trocar passes with the Prolift is that the nerves could be damaged from the trocar passes, yes or no?
A. Yeah, but I have to quantify that by saying that overall the risk of nerve injury with a trocar-based repair, in my view, is less.
Q. Okay. Would you agree with me that a trocar-less system, such as the Prosima device or the Elevate device,

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eliminates the risk of nerve damage specifically from trocar passes, correct?
And I'm just asking about trocar passes.
A. Again I will answer "yes" to that question with the previous qualifications in place.
Q. Now, Doctor, I notice that your expert report lists the clearance date for the Gynemesh PS product, right?
A. I believe it does.
Could you refer me to the page?
Q. Maybe.
Page 5.
A. I think it's 2000-2002, right?
Q. Yeah. I don't think you cited the specific date.
It says: "In 2000-2002 Gynemesh PS received FDA clearance for use in prolapse repairs."
Do you see that?
A. Yes, I do.
Q. Did you list anywhere in your expert report the clearance date for the

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Prolift kit?
A. I don't know if I did, but I believe it was 2005.
Q. It wasn't 2005. It was 2008. I'll represent that to you.
MS. KABBASH: What's the year you're representing on the record?
MR. FAES: 2008.
A. And the question was?
Q. Is there any particular reason why you didn't note the clearance date of the Prolift device in your expert report?
A. No particular reason that I know.
Q. Were you aware that the Prolift device was marketed without FDA clearance between 2005 and May of 2008?
MS. KABBASH: Let me just state an objection first as to the form, lack of foundation.
And also I'd just like to state a standing objection to any questioning with regard to the FDA status, regulatory status, or 510(k)

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clearance process, as Judge Goodwin has already ruled that all of such issues are inadmissible at trial and therefore should not be pursued at this deposition.
I don't want to keep interrupting you, so I'm going to state that.
MR. FAES: I'll just state for the record that a lot of these cases have been remanded and it's become clear that not all judges agree with Judge Goodwin's decision or feel bound to follow them. So I have to do it just in case the trial judge doesn't agree with Judge Goodwin.
MS. KABBASH: Okay. Well, I'm just going to stand by my objection based on the rulings we've received and have been applied at all trials in the federal courts thus far.
BY MR. FAES:
Q. Doctor, when you use a -- well, first of all, I'm not sure if I got the

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answer to the question.
Were you aware that the Prolift device was marketed without clearance by the FDA between 2005 and May of 2008?
A. I wasn't aware of it then. I'm aware of it now.
Q. When you as a physician select a medical device to implant in a patient, do you do it with the assumption that the device is being legally marketed by the company?
MS. KABBASH: Objection.
A. Legally marketed by the -- yes, I agree -- I put in devices or use products that I believe have been legally marketed.
Q. If a physician were to use it, knowingly use a device that they knew was not legally cleared by the FDA, do you believe that that would be below the standard of care?
MS. KABBASH: I just want to add to my standing objection that this line of questioning goes beyond the

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scope of Dr. Wagner's opinions. He is not offering opinions on compliance with regulatory standards. He's not offering opinions on compliance with standards of care of medical malpractice.
BY MR. FAES:
Q. Do you need the question repeated?
A. Please.
MR. FAES: Can you read it back, Court Reporter?
(The requested portion of the record was read by the Court Reporter.)
A. So, let me -- let me first state I'm not a regulatory and I do not have an in-depth knowledge of the regulatory requirements from the FDA and the companies.
If I'm using a device that's brought on to the American market, I'm using it with the assumption that either the appropriate pre-market studies have been done or it's based on a predicate

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device that has been approved by the FDA and that the predicate device was associated with appropriate pre-marketing testing.
What qualifies something as being eligible for 510(k) status or not is not my area of expertise, and I would leave it to the FDA, the companies, and the regulators to sort out those complicated issues.
Q. Do you agree with the viewpoint that there is a need for more rigorous studies regarding the safety and efficacy of mesh kits, like Prolift?
MS. KABBASH: Objection to form.
You're referring to all transvaginal prolapse mesh kits?
A. I think there's always a desire to improve upon our studies, and I think when it comes to vaginal mesh repairs, I understand the FDA's position that they want more rigorous studies of these kits and that that was their driving force behind moving, changing the class II to

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class III. I understand their position. I think that it is always valuable to have more data.
I also believe that not having a trocar-based system on the market has been an extreme detriment to my patients, and I think people have probably unnecessarily suffered as a result of not having that option available. So I think there's always a balance, but I understand the FDA's position and I understand why they did what they did. I just think that not having a trocar-based system available is not in the best interest of my patients.
Q. Do you know why Ethicon removed the Prolift from the market?
MS. KABBASH: Object to the form.
MR. FAES: Strike that. Let me re-ask it.
BY MR. FAES:
Q. Do you know why Ethicon stopped selling the Prolift?
A. Well, I think it was a business

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decision. I don't think it was -- it was a business decision.
Q. Do you know what the business decision was based on?
A. I think that, like most business decisions, it's probably based on the value of a product line and whether it's worthwhile or not.
You know, I'll give you an example that we've known for 30 years that Diclegis is the best drug to treat hyperemesis in pregnant ladies, but it's been unavailable in the U.S. market because every single drug company made a business decision that it would not be profitable to market this drug, and it's the only drug approved by the FDA to treat hyperemesis in pregnancy.
So, companies make business decisions based on the market, but also the medical-legal market, and Diclegis is a perfect example of that. Great drug that works beautifully, proven safe, and nobody will market it because it's not a

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good business decision.
Q. Would you agree with me that in order to keep selling the Prolift in the United States after 2012, Ethicon would have been required to conduct more rigorous studies regarding the safety and efficacy of that device?
MS. KABBASH: Objection to form.
A. Again, I have trouble with the term "more rigorous."
My understanding is that the FDA wanted several years of clinical follow-up on patients for the transvaginal mesh kits and they were not satisfied with the years of, five, seven years of follow-up that currently existed in the medical literature.
But again, I have a little trouble answering the question because it sort of requires that I get into the mind of the regulators at the FDA.
There was five to seven year data available on Prolift. The FDA wanted more data, is the best that I could

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summarize.
Q. So, would you agree with me that in order for Ethicon to continue selling the Prolift after 2012, they would have been required to collect additional clinical data, correct?
A. Yeah, or present additional clinical data. I don't know if -- again, I'm not the regulator. I don't know if the FDA would have been happy for them to re-analyze the clinical data that was out there. I just don't know. I don't know what the FDA was specifically looking for. I don't know if they wanted prospective data from that point forward or if they were willing to look at studies that had been done in the past. But the FDA's position was they wanted more data on those products that were on the market and they were not willing to allow a vaginal mesh kit to come to the market without pre-marketing data.
Q. Do you know whether or not the cost of collecting additional data on the

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Prolift in order to keep selling it in the United States was one of the factors they considered in making the decision to no longer sell that product?
MS. KABBASH: I'll object that it goes beyond the scope of Dr. Wagner's opinions.
You can answer if you can.
A. I don't know that I'm qualified to analyze the business plan of Gynecare vis-a-vis the FDA, the U.S. market, the medical-legal environment, and adding all that up in terms of a business proposition.
Q. If the Prolift device --
MR. FAES: Strike that.
MS. KABBASH: Are you okay to keep going without a break?
MR. FAES: We've got about half-hour left. This would be a good time for a break.
(Recess taken from 9:57 a.m. to 10:04 a.m.)

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BY MR. FAES:
Q. Doctor, we're back on the record after a short break.
Are you ready to proceed?
A. I am.
Q. So, Doctor, on page 34 of your report, you list a known body of potential risk and adverse events that are common to all forms of surgical treatment of prolapse. As you stated, and transvaginal mesh is no exception.
Are you on that page?
A. Yes, I am.
Q. So, you list a litany of risks and then you state that: "These risks of prolapse surgery are widely known by surgeons based on their training and based on the fact that they are reported in the published medical literature."
Do you see that?
A. I do.
Q. Is that an opinion that you intend to offer in this case?
A. Yes.

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Q. So, is your opinion that these risks are widely known by surgeons at all times during the marketing of the Prolift between 2005 and 2012?
A. Yes, and again we're talking about pelvic reconstructive surgeons, surgeons who do this type of surgery, yes.
Q. Have you done any kind of study or analysis to determine what percentage of pelvic floor surgeons did in fact know of all these risks between 2005 and 2012?
A. That's a funny question because it's an inherent part of the training. I mean, if you look at the surgical training that we receive as residents and then as fellows, people that do this type of surgery, this is part of the training. It's in the textbooks. It's in, you know, Te Linde's Operative Gynecology. The complication rates, wound healing, these are all subjects that are part of normal surgical training. It's in Danforth's books on operative gynecology. So it's part of our board questions. It's part of

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our -- it's part of what we're tested on.
So, to have a study on something that's supposed to be inherent to what you know, so you're asking sort of the question -- is the question is there post-marketing surveillance on whether the pelvic reconstructive surgeons have learned what they're supposed to have learned? Is that what the question is, in a way?
Q. Well, my question is have you ever done any kind of study or analysis to determine what percentage of pelvic floor surgeons did in fact know of all these risks in, say, 2012?
A. Again, that's such a funny question.
No, I've never done a study that looks at whether the pelvic floor surgeons learned what they were supposed to learn about pelvic floor surgery. It just doesn't make sense to me, that question.
Q. So, when you say that they are widely known by surgeons, is it your

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opinion that 100 percent of pelvic floor surgeons know of all these risks, or not?
MS. KABBASH: Objection.
A. I would like to think that my field is perfect, but I'm sure it's like every other field. There's probably not competent people in my field, just like there's not competent lawyers and not competent firemen and not competent cops. But what you're asking is part of our inherent training, and so if I -- if I could assert the word "competent" and "well-trained," then yes, the answer would be 100 percent.
Q. So, it's your opinion that if a physician in a particular case testified that he didn't know of one or more of these risks when he implanted the Prolift that that physician wasn't competent?
MS. KABBASH: Objection.
A. I'm not sure what risk you're referring to because our initial discussion was talking about general risks of vaginal surgery. So if we're --

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Q. I'm referring to any of the risks that you have listed in paragraph 1 of page 34 of your report.
A. Yes, I think that a pelvic surgeon who does pelvic reconstructive surgery realizes that that list of things that I laid out there are potential complications of pelvic repair surgery with or without using mesh. And I would be surprised, and maybe I'm thinking too highly of my own field, that if a board certified urogynecologist in pelvic reconstructive surgery didn't know those things, I would certainly be disappointed.
Q. But my question is specifically if a pelvic floor surgeon testified that prior to implanting the Prolift that he didn't know one or more of these risks, would it be your opinion that that physician wasn't competent because he didn't know one or more of these risks?
MS. KABBASH: Objection.
A. Again, I just go back to my previous answer. I think these are

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general risks that are well-known and I would be surprised.
I think competency comes into passing your boards, taking your tests, being approved. Competency is something judged by the board, the American boards, as well as the individual hospitals and their credentialing. But I would be surprised if a board certified pelvic surgeon didn't know those things.
Q. Could a reasonable pelvic floor surgeon not know of one of these risks prior to implanting the Prolift?
MS. KABBASH: Objection.
A. I think these are straightforward risks.
Again, I would be surprised. I mean, if you listed ten things and one surgeon somewhere said "I didn't know about urinary retention," I'd be like oh, really? That's pretty common. I'd be surprised. If he didn't know about nerve damage, I'd be like really? I'm surprised. Hematoma, I'd be like really?

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Any surgery causes hematoma. I'd be surprised.
I just -- I don't find this list to be that hard. So I would be surprised.
Q. Have you made any kind of effort to go out into the medical community or in the literature and actually look at surveys or studies of what physicians actually did or didn't know of these risks to see if your reaction of surprise is justified or if there are in fact many physicians who don't know all of these risks?
A. Again, if we're narrowing this down to board certified, fellowship-trained female pelvic reconstructive surgeons, I had be surprised if they weren't familiar with all of these complications with any type of vaginal repair, be it mesh augmented or not.
Q. But you haven't specifically studied that issue with regard to what percentage of patients knew or didn't --
MR. FAES: Strike that.

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Q. You haven't specifically studied the issue of what percentage of pelvic floor surgeons did or didn't know of these risks, say in 2005 when the Prolift was launched?
MS. KABBASH: Objection.
BY MR. FAES:
Q. Correct?
A. Well, I don't know of a post-marketing surveillance study of doctors. By post-marketing, I mean like I'm saying it almost in jest because it would be post-marketing of their medical training. I just -- I don't know of -- I don't know of any study, and I certainly did not conduct a study to look at my colleagues to see whether they understood the basics of vaginal surgery. I just -- it's a funny question, is my best answer.
Q. Would you agree with me that excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening, and/or shortening is a potential adverse reaction of the

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Prolift mesh?
MS. KABBASH: Objection to form.
A. Yeah, I think that's on the -- could you repeat that question?
But I think you're reading from the IFU, are you not?
Q. Yeah.
A. Yes.
Q. First of all, would you agree with me that excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening is a potential adverse reaction of the Prolift mesh?
A. Yes.
MS. KABBASH: Objection.
A. I think it's listed in adverse reactions. But again, it's adverse reactions and it's a potential complication of Prolift surgery and it's a potential complication actually of vaginal surgery.
Q. Do you think that adverse reaction should be listed in the adverse

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reaction section of the IFU for the Prolift?
MS. KABBASH: Objection; compound.
A. I think that -- I think that what gets listed in the IFUs is sort of a subject of debate among the FDA regulators and the company, but I think that that particular sentence that you read to me is applicable to vaginal surgery with not mesh, non-mesh operations also.
Q. So you think that excessive contraction or shrinkage of tissue surrounding mesh is applicable to non-mesh surgery?
A. No. I think everything that you just said there subtracting the word "surrounding mesh" is applicable to non-mesh surgery.
Q. Do you think that that adverse reaction needs to be included in order for the instructions for use, or the IFU, for the Prolift to be adequate?
A. Again, I fall back on the fact

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that I'm not a regulator or responsible for knowing what should be in an IFU.
And again, I think there's some give-and-take between the regulatory bodies and the companies on that. But that seems to be reasonable, but I would preface it by saying that that is an adverse reaction that can occur without a mesh product. So that entire statement holds if you were just to remove the part about the mesh, the two words that include mesh.
Q. Do you think it would be reasonable for a physician, say in 2005 when the Prolift was launched, if that physician said he didn't know that that was a potential adverse reaction of the Prolift mesh?
A. Again, I don't see that as an adverse reaction of the mesh as much as I see that as an adverse reaction of vaginal surgery, and in the case where you put the mesh in, it involves the mesh. But you can have scar tissue retraction and things

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that occur with just native tissue repairs too. They just wouldn't involve mesh.
So, I think that to turn that around and say that we know you could have excessive scarring and contraction with non-mesh surgeries and to somehow think that we wouldn't see that if we put a piece of mesh in there is a little bit hard to believe.
So, if a surgeon understands that there's contractures that can occur and contraction that occurs as part of normal wound healing and to expect that that wouldn't occur if you do a mesh augmented operation, that doesn't make a lot of sense to me. Contraction's a normal part of wound healing. Contractures can occur when normal wound healing gets out of hand. You don't need mesh there. And to think that it wouldn't happen just because I put a piece of mesh in there, that it would change the wound healing process, that doesn't make a lot of sense to me.

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Q. Do you agree with me that exposed mesh that causes pain to the patient's partner during intercourse is a potential adverse reaction of the Prolift mesh?
A. Yes, of any vaginal mesh repair, period.
Q. Would you agree that that's a risk that's unique to repair with mesh surgery?
A. Yes, I would.
Q. Do you think that all physicians, well-trained pelvic floor physicians, knew of that risk between 2005 and 2012 when the Prolift mesh was marketed?
A. It's hard for me to answer that.
MS. KABBASH: Objection to form.
A. But I would say that any physician that was implanting vaginal mesh, or for that matter abdominal mesh, who wasn't aware of the risk of mesh erosion in the small number of patients probably didn't have a great handle on the

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medical literature and the complication rate of the operation they were doing.
Q. But I'm not just talking about mesh erosion, Doctor. I'm specifically talking about exposed mesh causing pain or discomfort for not the patient, but the patient's partner during intercourse.
Do you think that all well-trained physicians knew of that risk between 2005 and 2012 when the Prolift mesh was marketed?
MS. KABBASH: Objection.
A. I kind of consider that one in the same. I think if you know that there is a risk of erosion, well, then you probably know that erosions can cause pain, can cause bleeding, can cause dyspareunia for the patient and her partner. You know what erosions can do and what the symptoms of an erosion can be. I kind of consider that one in the same.
So it would be farfetched for me to imagine that somebody can understand

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that there was a risk of erosion but not understand what that meant in terms of signs and symptoms. Again, I would struggle with that concept.
Q. Have you ever studied the question of what percentage or number of well-trained pelvic floor surgeons knew that exposed mesh could cause pain or discomfort to the patient's partner during intercourse, say in 2005 when the Prolift was launched?
A. Did I ever study that?
Q. Correct.
A. I didn't study that.
Q. And I assume your answer is the same with regard to the other years when the Prolift was marketed, 2006 through 2012, correct?
A. No, I didn't perform studies on Prolift, period, or studies of the surgeons who were implanting Prolift, period.
Q. Do you believe that that is a adverse reaction that should be warned

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about in the IFU, or instructions for use?
A. Again, I consider a mesh erosion as a mesh erosion.
Do I think that it's necessary to list all the symptoms of a mesh erosion: pain, bleeding, dyspareunia, discharge, partner dyspareunia? I don't know that it's -- I don't know that that's necessary, and I come back to I'm not the regulator, I'm not the people doing this, but it would sort of to me be like that I would have to list all the symptoms of a hematoma. So you can say that you get blood loss in hematomas, but do I have to list, you know, nerve palsies, numbness, tingling, motor dysfunction, transfusion, blood loss, weakness, dizziness, syncope, all the symptoms of a hematoma, or is it just adequate to say hematoma? I think that in my opinion, and I'm not the regulator or the people making the rules, if you say mesh erosion, I don't think you need to list all ten symptoms associated with the mesh erosion any more than you

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have to list all 25 symptoms associated with hematoma.
Q. Well, you've offered the opinion in this case that the IFU, the professional education materials, and the Prolift surgical guide, and the Prolift surgeon's resource monograph --
MR. FAES: Strike that. It says accurately, not adequately.
Q. Would you agree with me that scarring which results in implant contraction is a potential adverse reaction of the Prolift device?
A. Yes. And again I would quantify that by saying that scarring that results in contraction, with or without an implant, can lead to significant problems.
Q. Do you think that the fact that there is an implant that actually contracts within the scar presents unique risks in a surgery involving transvaginal mesh as opposed to one that doesn't?
A. No, I don't think the -- the implant is inert. I don't think the

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implant contracts. The scar tissue around the implant can contract and cause contracture that's abnormal, but the implant itself is inert. It doesn't contract.
Q. So you don't think that implant contraction is a potential adverse reaction of the Prolift mesh?
A. No, that's not what I said. I said you can have contraction with an implant in it, but the implant's inert. It's not contracting. The scar tissue around it is contracting. So you can have scar contraction with an implant as a complication, but it's not the fault of the implant. It's the scarring.
Q. Doctor, on page 30 of your report you state that you believe that there's no credible body of evidence published in the medical literature that --
MR. FAES: Strike that. Let me back up real quick.
Q. On page 40 of your report you

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state that you believe that the documents, the IFU, the professional education materials, the Prolift surgical guide, and the Prolift surgeon's resource monograph accurately warn of the potential risk of these devices; is that correct?
A. Yes.
Q. Is it your opinion in this case, or are you offering an opinion in this case that the IFU for the Prolift adequately warns of the potential risk of the device?
A. Okay. I have to give a two-part answer to that.
First of all, as I read this, I would have to expand this from the use of these slings to include vaginal mesh repairs because I think this was part taken from my TVT expert report. So I would just amend that by adding vaginal mesh repairs in there.
And adequate to me, again, I think is a function of what the FDA and the regulators want and what the company

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does to follow their guidelines. I don't determine adequacy in terms of the documents. I do think they're accurate, but adequacy is determined by the regulators, company, the FDA, the people that are involved in regulating what should be in an IFU or not.
Q. So you'd agree with me that you don't have the expertise necessary to offer an opinion as to whether the warnings in the IFU for the Prolift is adequate, just whether they're accurate, correct?
MS. KABBASH: Objection.
A. I think that I -- I can speak to the fact that I think they accurately reflect, in my opinion, basic surgical risks involved with implanting the mesh product.
But again I come back to the definition of "adequate" is really based on what the FDA, the regulators, and the company decide is adequate. I think that the IFU for any product should certainly

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include risks that are known to occur with that product, but what other risks might be associated with it that might be common knowledge in medical textbooks, amongst surgeons, among the peer review literature, that part of it I think is a gray zone, and whether it's adequate to include some of that or none of that to me is a function of the regulators and the company and the FDA.

Q. Do you feel like you have an expertise enough to offer an opinion as to whether the warnings in the IFU for the Prolift in this case are adequate?

A. Again, I think they -- again, adequacy is defined by other people, not by me. But I think from a clinical perspective, I found that these warnings accurately warned of the potential use, the risk of the potential use of these slings. I think they were accurate and I felt that they summarized the relevant risk. Whether it's adequate or not is a function of the regulators.

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Q. So, can you answer this question for me yes or no: Are you offering an opinion to a reasonable degree of medical certainty in this case that the warnings in the instructions for use for the Prolift IFU are adequate?

A. Again, I have to have you define "adequate" for me.

Are you talking about basically do they meet the standards of the FDA? Did the FDA and the regulators sign off on them? Because then they're adequate.

Do I think from a clinical perspective that they were accurate and summarize the relevant risk? Yes, I do. But adequate is a governmental, regulatory decision.

Accurate and reasonable summary of the relative risks is a clinical decision that I can make based on my clinical experience and review of the literature, and I think that they accurately reflected a reasonable summary of the risks.

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Q. Doctor, on page 30 of your report you state that you don't believe that there's any evidence that the Prolene mesh is cytotoxic; is that correct?

A. Yes.

MS. KABBASH: I'm sorry, which page, 38?

MR. FAES: 30.

THE WITNESS: 30.

MR. FAES: I may have the page wrong. It's 29 into 30. My apologies.

So, I guess let me restate the question.

BY MR. FAES:

Q. You state on pages 29 and 30 that you disagree that the Gynemesh PS mesh is cytotoxic?

A. I disagree with plaintiff's assertions that it is cytotoxic, yes.

Q. Would you agree that one of the potential effects of exposure to a cytotoxic compound is necrotized tissue rounding the mesh?

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A. No, not necessarily because you could have necrotized tissue from just lack of blood flow, peripheral damage, heat, from cautery, from intrinsic disease such as diabetes. That's why people lose their limbs with diabetes, their legs, their toes get necrotic. So that's not due to mesh. You could have cell death from a lot of sources that's not --

Q. Yeah, I understand all that, Doctor. But my question is is that the tissue turning necrotic is one clinical way that exposure to a cytotoxic substance can manifest itself, right?

A. Well, to the exclusion of all the other things that I just said that could potentially be causes. So if you want to exclude every other known cause of necrotic tissue and say have I effectively excluded everything that could cause this and then you're in proximity with something, you have to assume that potentially that could cause it. But again, just proximity doesn't -- doesn't

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prove anything and it's -- I don't know how you -- I don't know how you'd study the -- I don't know how you'd eliminate all the other causes that could cause necrotic tissue there. So I think clinically that statement is way too broad to accept as blanket, yes.

Q. Would you agree with me that every time that you'd been asked as an expert witness to examine the safety and efficacy of a mesh device for the treatment of pelvic organ prolapse or stress urinary incontinence you found that that device was safe and effective?

MS. KABBASH: Objection.

A. Could you repeat that question again, or have her read that back?

MR. FAES: I'll just restate it.

BY MR. FAES:

Q. You'd agree that every time you've looked at a mesh device for the treatment of stress urinary incontinence or pelvic organ prolapse as an expert witness you've concluded that that device

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is safe and effective, correct?

A. No.

Q. In what case did you serve as an expert witness where you found that a mesh device was not safe and effective?

A. I apologize because I misinterpreted your question.

In an expert witness capacity, the answer is "yes."

As a general rule, the answer is "no." There are some implants, classically Gore-Tex was an implant that we used late '80s, early '90s that was not good to neighboring tissues. It didn't allow the appropriate ingrowth and promoted infection and breakdown and erosion.

So, there are some implants that lend themselves to higher complication rates. But as an expert witness testifying for the meshes that I've been asked to render an opinion on legally, the answer is "yes."

Q. So you'd agree with me that at

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least the Gore-Tex mesh to you had a complication profile that was unacceptable to you, correct?

A. Yes, especially for sacrocolpopexies.

Q. How high would the complication rate need to be on the Prolift before you decide that its complication rate was unacceptable to you?

MS. KABBASH: Objection.

A. That's a almost -- there's no rate here. It's almost impossible to -- to put a number like that. This isn't a number -- this isn't a number thing.

I can tell you that the use of Gore-Tex for sacrocolpopexies was associated in the literature with higher rates of complications than other products, and we have good meta-analysis, good long-term data, high levels of the pyramid data showing complication rates associated with Prolift, and I'm happy with that complication profile, and I think for the appropriate selected

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patients, it's an excellent procedure, and it was an excellent procedure.

Q. So, what objective standard are you applying to determine that the Prolift is safe and effective while concluding that the Gore-Tex is not safe and effective?

MS. KABBASH: Objection.

A. The objective standard is -- is the objective standards that form my medical opinions: my training, my surgical training, my surgical experience, my teaching, my review of the literature, my attendance at conference, my review of cases presented at conference. The body of medical literature that exists out there is my objective standard. And then as I said in my expert report, rating that body of literature based on quality of evidence is my objective standard.

Q. So, in terms of complication rate, you'd agree with me that there's no numerical number of complications that you can give me to where you'd feel that the

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Prolift device was not safe and effective, right?
MS. KABBASH: Objection.
A. I think that there are -- it's hard to separate the individual from the procedure. There were clinical situations where native tissue repairs are appropriate, where mesh repair is appropriate vaginally, where an abdominal mesh repair is appropriate, and I don't think we're trying to pound all patients through the same operation. If there's a surgeon doing only one operation, then I don't think they're serving their patients well.
You know, it's like -- and in terms of complication rates, you know, we give poisons to people who have cancer because -- because the complication rate of the cancer is much greater than the complication rate of the poison we're giving them. So it's always a measure of what you're treating them versus the complication rate. I wouldn't give

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somebody, you know, Cytoxan, which is a poison, even if it did treat pelvic prolapse because I have much lower risk -- lower risk treatments for that, but if they have breast cancer, yeah, I'm going to give them that otherwise the breast cancer's going to kill them.
So, we're always relating what we're treating people with to the underlying disease process and we're looking to benefit the patient overall.
Q. Well, here we're talking about pelvic organ prolapse and the Prolift.
A. Right.
Q. So, how high would the complication rate need to be for a device to treat pelvic organ prolapse before you'd say this isn't acceptable to me, it's not safe and effective?
MS. KABBASH: Objection; asked and answered.
A. I agree. I think I've answered it.
Q. So even if the complication rate

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were 100 percent, it could potentially be, the Prolift could potentially be safe and effective applying your standard?
MS. KABBASH: Objection.
A. Again, I think we're looking at the published literature, the rates of complications as we know it compared to other procedures, including non-treatment and analyzing the patient and her disease process in light of all of that and providing options.
Q. And there's no numerical standard that you can articulate as you sit here today to where you would determine the Prolift or a device like the Prolift to not be safe and effective?
A. I don't think of it as just a numerical standard like that.
MS. KABBASH: Objection.
A. It's way too broad. It's way too -- it's clinically useless because complications could be anything from, you know, the most minor thing to life-threatening. So you can't even put a

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number on it 'cause complications could be anything. It's just not a credible -- it's not a realistic way to look at this.
MR. FAES: I'd love to keep debating, but I think I'm out of time.
MS. KABBASH: Doctor, I just have a few follow-ups for you.
EXAMINATION BY
MS. KABBASH:
Q. If you could turn to page 45 of your report. It's actually the last page with your signature. And take a look at opinion 8.
Do you have that, Doctor?
A. I do.
Q. You were asked several questions earlier about whether it was your opinion that the warnings and risk information provided in the Prolift materials were adequate.
Do you remember that line of questioning?
A. I do.
Q. Okay. Let me just read into the

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record the first line of opinion 8. It says: "The possible risks of Gynemesh PS and the Prolift products are appropriately described in their instructions for use, the patient brochures for the Prolift products, and in Ethicon's professional education materials."

Do you see that?

A. I do.

Q. Does that continue -- is that still currently your opinion as of today?

MR. FAES: Object to form; leading.

A. Yes.

Q. Do you hold that opinion to a reasonable degree of medical certainty?

MR. FAES: Object to form.

A. Yes.

Q. The next sentence says: "These materials properly reflect the risks that are reported in the high level medical literature and appropriately account for the common knowledge of trained specialists."

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Do you see that?

A. Yes.

Q. Is that your opinion as of the time you wrote the report?

MR. FAES: Object to form.

A. Yes.

Q. And does it continue to be your opinion today?

MR. FAES: Object to form.

A. Yes.

Q. Do you hold that opinion to a reasonable degree of medical certainty?

MR. FAES: Object to form.

A. Yes.

MS. KABBASH: Do you hold that opinion to a reasonable degree of medical certainty, object to form?

Do what you got to do. Okay.

MR. FAES: Leading. It's a continuation of the previous.

MS. KABBASH: Okay.

MR. FAES: Come on. You guys object to everything and I just ignore it like buzzing in my ears.

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MS. KABBASH: I don't agree with that, but whatever. Let's move on.

BY MS. KABBASH:

Q. You say these materials properly reflect the risks that are reported in the high level medical literature.

Can you just explain to me what you're referring to when you opine that? What process did you undertake to arrive at that conclusion? That's my question?

A. That's what's referred to as the Oxford Pyramid of Evidence. It looks at the quality of studies, ranks them in terms of least valuable all the way up to most valuable, anywhere from expert opinion to meta-analysis, systemic reviews, and the meta-analysis systemic reviews represent what's thought to be the highest quality evidence, especially when they're well done.

Q. In reviewing the IFUs for the Prolift, did you review the language of the IFUs in comparison to the clinical literature on Prolift and Gynemesh PS?

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A. Yes, I did.

Q. Did you find that the materials --

MS. KABBASH: Strike that.

Q. Did you find that the Prolift IFU appropriately and accurately reflected the risks that were reported in the medical literature?

MR. FAES: Object to form.

A. Yes, I did.

Q. Did you also compare the language of the warnings in the Prolift IFU and the adverse events to your own surgical experience with Prolift?

MR. FAES: Object to form.

A. I think that what's in the IFU and what's in the medical literature does so square nicely with my clinical experience over the years.

Q. Doctor, if you could go to page 34 of your report. You have a discussion there of mesh exposure and erosion.

Do you see that?

A. Yes.

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Q. And you previously testified --
MS. KABBASH: Strike that.
Q. You were asked questions about a mesh exposure rate with regard to the Prolift, and I think that you offered the range of 2 to 5 percent.
Do you recall that?
A. I do.
Q. What source were you, source or sources, were you basing that on when you offered that range?
A. I think that's just my general reading of the medical literature, particularly the high quality literature. And I also think it reflects a more modern -- modern. More recent studies because I think that in general, and this also correlates with my experience, as surgeons get better doing vaginal mesh repairs and develop techniques for doing vaginal mesh repairs, our erosion rates have decreased. So there are erosion rates in the literature that go up there, they go up like 15, 18, 20 percent, in

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that range, but I think that overall it's my reading of high quality medical literature in conjunction with my experience that an experienced pelvic surgeon with experience with transvaginal mesh probably has a significant erosion rate of maybe 2 to 5 percent when dealing with vaginal mesh repairs, not slings, but vaginal mesh repairs.
Q. In forming your opinions, did you review and consider studies that reported mesh exposure rates higher than 5 percent?
A. Yes.
Q. And here in your report on page 34, do you indicate that occurrence rates of mesh exposure are typically under 18 percent?
A. Yes.
MR. FAES: Object to form.
BY MS. KABBASH:
Q. If you look at page 35 in the last sentence of the top paragraph, do you discuss there what exposure rates are

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referenced in the Prolift surgeon's resource monograph that was put forth by Ethicon?
A. Yes, I do.
Q. And what exposure rates are provided in that monograph?
A. Between 3 and 17 percent.
Q. And in forming your opinions about the safety and efficacy of Prolift, Dr. Wagner, did you take into consideration studies that report exposure rates higher than the 2 to 5 percent that you discussed before?
A. Yes.
Q. If you turn to page 12 of your report.
You were asked some questions earlier about the weight of Gynemesh PS and specifically I think on what information you based your assessment that Gynemesh PS was a low-weight mesh.
Do you recall that?
A. Mm-hm.
Q. Do you recall being asked if you

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could point to a source for that information?
Do you recall that?
A. Yes.
Q. Okay. Here in your report you make the statement: "Gynemesh PS is a low-weight Amid type 1 polypropylene mesh."
Is there an article that you've cited for that proposition?
A. Yes, the Jones article.
Q. And is that the Jones article called "Tensile properties of commonly used prolapse meshes"?
A. Yes.
Q. Was that article published in the International Urogynecology Journal?
A. Yes.
Q. Is the International Urogynecology Journal a peer-reviewed publication?
A. Yes.
Q. And is that one of the sources that you were relying upon for your

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assessment of Gynemesh PS as a low-weight material?
A. Yes.
Q. In addition to what you testified to earlier?
A. Yes. They describe it as low-weight.
Q. You testified earlier in response to questioning from counsel about, I'm paraphrasing this to some extent, but you said that in a healthy woman without certain comorbidities, and in light of the advent of minimally invasive techniques, you would opt to perform an abdominal surgery versus a vaginal surgery to treat prolapse.
Did I accurately summarize that?
A. I think so, yes.
Q. Within the context of your answer, what minimally invasive abdominal surgery are you referring to?
A. Using the robotic or laparoscopic approach to do a sacrocolpopexy.

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Q. And what is it about the --
MS. KABBASH: Strike that.
Q. At the time that Prolift was introduced to the market, was that form of minimally invasive abdominal surgery, in particular the robotic surgery, available at that period of time?
A. If it was, it was only in one or two centers. It was basically in its infancy. Laparoscopic surgery had been around for a while, but there were very few surgeons capable of doing a laparoscopic sacrocolpopexy.
Q. You testified earlier that native tissue repairs are an alternative to Prolift.
A. Correct.
Q. Is a native tissue repair always the best alternative to Prolift for a given patient?
MR. FAES: Object to form.
A. Never always. It's an alternative. In some people it might be the best approach, but never is it always

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the best approach.
Q. And why with some patients is Prolift a better alternative to native tissue repair?
A. People who are at high risk for recurrence, either based on their family history, their personal health history, such as the history of hernias, people that have already had a vaginal repair that has now failed, people with a global defect across the whole vagina, people who have -- who are of a young age with a family history for prolapse, these are all patients, to list a few, risk factors who are at high risk for failure or recurrence and those are people who may be best served by a mesh augmented repair and not a native tissue repair.
Q. I think you also testified that an abdominal sacrocolpopexy is an alternative to Prolift.
Is abdominal sacrocolpopexy always a better alternative to Prolift in patients?

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A. No.
Q. And why is that?
A. Because you can have patients for whom a sacrocolpopexy is potentially a much more risky procedure based on their medical history, surgical history, their age, their comorbidities, heart disease, and the vaginal approach may make much more sense in that particular patient population.
Q. I think you testified in response to one question that you were asked does eliminating trocars eliminate the risk of injury associated with trocars, and I believe you said yes.
A. Yes.
Q. Is there a downside from the perspective of safety to eliminating trocars such as the trocars used in the Prolift device?
A. Yes. I think that if you look at trocar-based repairs, in my opinion, the advantage of the trocar systems, like Prolift, like the Exair, are that you can

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make smaller incisions, there's less dissection, less need for hysterectomies and other concomitant procedures and allows you to place the mesh in the appropriate compartment in a very minimally invasive way, and by doing it minimally invasively, you minimize local trauma such as bleeding, nerve damage. You minimize pain. You speed the recovery.

So, while the actual placement of the trocar is potentially a surgical maneuver that can add a unique risk, the overall benefit of the trocar-based systems is a much lower complication profile and lower morbidity overall.

Q. I just have one more area I want to ask you about.

You were questioned earlier about what risks were widely known among surgeons, and you were asked if you had performed any study to determine what surgeons actually knew at a given time.

Do you recall that line of

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questioning?

A. I do.

Q. Turn to page 38 of your report.

In this part of your report, do you have a section called "Commonly Known Risks of Surgery"?

A. Yes.

Q. Did you perform an analysis of the published medical literature to assess what risks were reported on and available in the publicly available medical literature?

MR. FAES: Object to form.

A. Yes.

Q. Do you discuss studies that discuss the risk of mesh erosion in this section of your report?

MR. FAES: Object to form.

A. Yes.

Q. Do you list here studies that were published between 1997 and 2006 that discuss the risk of mesh erosion?

MR. FAES: Object to form.

A. Yes.

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Q. On the next page, on page 39, do you list studies that discuss the risk of pain with intercourse and sexual dysfunction that were available in the medical literature?

A. Yes.

Q. And with respect to the articles about pain with intercourse, were these articles that you reference, do they start in 1961?

A. Actually, they go back to 1961, yes.

Q. And do they go --

MS. KABBASH: Strike that.

Q. Doctor, is the published medical literature information that is out in the public and available for doctors to access?

A. Yes.

Q. And is your review of the published medical literature and the testimony you gave before about what is taught in surgical training the basis for your opinion about what is widely known by

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surgeons?

MR. FAES: Object to form.

A. Yes, including what's in textbooks, which would be part of normal medical and surgical training.

MS. KABBASH: I don't have anything else. I think we're done. Thanks, Doctor.

(Deposition adjourned at 10:55 a.m.)

ACKNOWLEDGMENT

STATE OF)
:ss
COUNTY OF)

I, JOHN R. WAGNER, M.D., hereby certify that I have read the transcript of my testimony taken under oath in my deposition of September 25, 2017; that the transcript is a true and complete record of my testimony, and that the answers on the record as given by me are true and correct.

_____
JOHN R. WAGNER, M.D.

Signed and subscribed to before me this _____ day of _____, 2017.

_____
Notary Public, State of

ERRATA

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CERTIFICATE

STATE OF NEW YORK
COUNTY OF NEW YORK

I, Marie Foley, RMR, CRR, a Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:

THAT JOHN R. WAGNER, M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 29th day of September, 2017.

_____
MARIE FOLEY, RMR, CRR

LAWYER'S NOTES

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